
*Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care*

**CONSUMER HEALTHCARE PRODUCTS ASSOCIATION**

*Formerly Nonprescription Drug Manufacturers Association*

March 19, 1999

Debra L. Bowen, M.D.
Deputy Director, Office of Drug Evaluation V
Acting Director, Division of OTC Drug Products
Division of OTC Drug Products (HFD-560)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Request for a Feedback Meeting OR FDA Participation in an Industry Briefing: [Docket Nos. 98N090337, 96N090420, 95N090259, and 90P090201]

Dear Dr. Bowen:

Further to our discussion at the CHPA Annual Meeting in Florida, I am writing to request either a Feedback Meeting on the recently published Final Rule on the format and content of the Information Panel or a CHPA-sponsored Industry-Briefing which would include the participation of the FDA team most closely involved in the development of the Final Rule and/or its future implementation. As I mentioned to you, it is vital that this meeting take place as soon as possible, and preferably before the end of April, 1999, given the urgent need for companies to bring into compliance a large number of SKU's affected by the Final Rule.

CHPA has long embraced the goal of making OTC labels even more consumer friendly, and on many occasions, beginning in earnest just before the September 29, 1995, public hearing, CHPA has provided FDA both detailed oral and written comments on the feasibility of various features of label readability that were addressed in the public dialogue and in the Proposed and Final Rules on OTC label content and format. Currently, our Committee of Label Coordinators, composed of key individuals in each of our member companies, is "test driving" the provisions of the Final Rule to determine the extent to which it is actually a fit for the marketplace. We understand that FDA did the same with certain of the labels that we submitted, and we in turn are looking at FDA's "refit" of those labels. Obviously, we both want to avoid a situation where there are many letters requesting exemptions to the Final Rule, thereby making the Final Rule a regulation of exemptions instead of broad applicability. We hope to bring this information forward during the time of the Feedback Meeting or the Industry-wide Briefing, as well as other questions and comments that our members will likely

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have and that we will compile in our preparation for the Feedback Meeting or Industry-wide Briefing.

I also mentioned to you that our main interest is in having this meeting as soon as possible. We do not wish to waste time in getting down to the business of implementing this rule nor do we wish to waste time in addressing aspects of OTC labeling of the Information Panel which may have been overlooked by all of us in the preparation of the Final Rule, but which will only come to light when the actual labels are "test driven" in the light of impending compliance dates. To this end, I suggested to you that we might hold the Industry-wide Briefing at an FDA site (e.g., the Parklawn Building) or at a nearby local hotel and that CHPA would be willing to run the meeting. If we run the meeting, we would ensure that all administrative aspects are taken care of and that invitations are extended to the entire industry – e.g., CTFA and CHPA members – as well as interested consumer and health professional groups. This would be a way to save government funds in an area that does not have user-fee support, and there is precedent for this in our Industry-wide Briefing which we organized in the Spring of 1996 after publication of the proposed labeling rule and which was attended by Dr. Michael Weintraub.

Whether done as a Feedback Meeting or as an Industry-wide Briefing administered by CHPA, the need is to have this meeting as soon as possible, and preferably before the end of April. We hope you and members of your team that are most familiar with the Final Rule and/or specifically involved in its implementation will attend.

In closing, this is a very important matter to our membership, and I look forward to your early response.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

cc: CHPA Label Coordinators
R. DeLap, M.D. (FDA)
T. Donegan (CTFA)
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OTC Dockets Management Branch

WS:jkq